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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/781,610		DENYER ET AL.	
	Examiner		Art Unit	
	Michael G. Mendoza		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-13 and 15-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9 and 15-38 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 11, filed 22 March 2004, with respect to the rejection(s) of claim(s) 1-4, 7, 9, and 21 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Romick 6082544.
2. Applicant's arguments filed 22 March 2004 have been fully considered but they are not persuasive. As to claim 13, the Applicant argues that Castellano does not teach an electronic data carrier which can be physically removed. However, in the claim, the limitation is an electronic input arranged remotely. The claim is not directed to the electronic data carrier, but to an electronic input. Castellano teaches a computer (electronic input) that is connected to the device via a data port 46. The computer is able to be disconnected and is also remote of the device. The Examiner also would like to point out the definition of "remotely" from Merriam-Webster Online Dictionary (<http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=remotely>).

Main Entry: **¹re·mote** 🗣️

Pronunciation: ri-'mOt

Function: *adjective*

Inflected Form(s): **re·mot·er; -est**

Etymology: Middle English, from Latin *remotus*, from past participle of *removEre* to remove

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1 : separated by an interval or space greater than usual <an involucre *remote* from the flower>

2 : far removed in space, time, or relation : DIVERGENT <the *remote* past>
<comments *remote* from the truth>

3 : OUT-OF-THE-WAY, SECLUDED <a *remote* cabin in the hills>

4 : acting, acted on, or controlled indirectly or from a distance <remote computer operation>; also : relating to the acquisition of information about a distant object (as by radar or photography) without coming into physical contact with it <remote sensing>

5 : not arising from a primary or proximate action

6 : small in degree : SLIGHT <a *remote* possibility>

7 : distant in manner : ALOOF

- **re·mote·ly** *adverb*

- **re·mote·ness** *noun*

As to claim 19, the Applicant argues that electronic data carrier of Wolf et al. is not separate from the drug delivery device, is not detachable from the delivery device and is supplied separately from the drug delivery device. The Applicant is pointed toward figure 1 showing an electronic data carrier 110 detachable from a drug delivery device 140. As to the argument that the delivery device is supplied separately from the drug delivery device, the limitation is not found within the claim. However, the Examiner points out that the electronic data carrier is usable with any conventionally available

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medicated dry powder metered dose inhalant dispenser (col. 4, lines 24-25). The data carrier could be obtained separately from the dispenser.

As to claims 22-38, the Applicant argues that both Wolf et al. and Eigler et al. fail to disclose that more medication is requested from a data center. However, Eigler et al. teaches an apparatus for communicating information. The apparatus is adapted to track the doses remaining and automatically reorder when remaining doses are low (col. 10, lines 60-65).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Romick.

5. Romick teaches a drug package comprising: a plurality of drug vials containing drugs, an electronic data carrier separate from the drug vial (col. 1, lines 49-50), the carrier including drug treatment information; wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of the drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the

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drug which is to be delivered; the number of treatments available from the drug package (col. 5, lines 16-35).

6. Claims 13, 15, 16, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Castellano et al. 5593390

7. Castellano teaches a drug delivery apparatus comprising: a delivery portion 28; an electronic input (col. 9, lines 15-26); a delivery controller; wherein the input is a radio frequency input which receives the treatment information from a data carrier at radio frequency (col. 9, lines 15-26); wherein the input is additionally arranged to transmit completed treatment information to the data carrier (col. 9, lines 15-26); wherein the drug delivery apparatus is one of a pneumatic nebulizer, a piezo-electric nebulizer and an ultrasonic nebulizer (col. 23, lines 9-12); and a medication chamber 16.

8. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. 5505195.

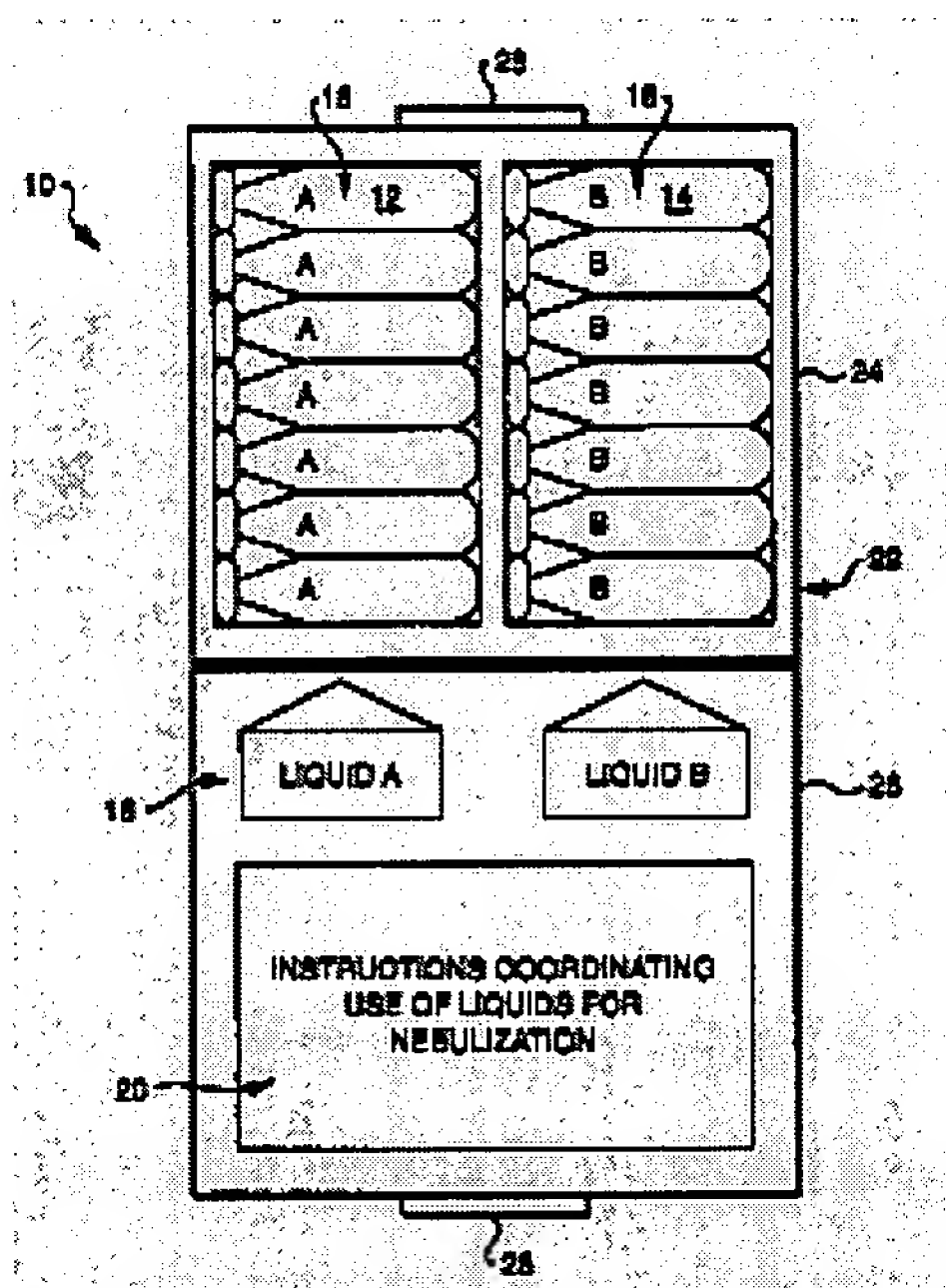
9. Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus comprising a memory located within the data carrier for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 41-58).

10. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Weinstein 6571790.

11. Weinstein teaches a method of operating a drug delivery apparatus comprising: supplying a plurality of vials of a drug for use with the drug delivery device apparatus;

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supply a data carrier separate from the vials and which includes treatment information; transmitting treatment information from the data carrier to the drug delivery apparatus; placing an amount of the drug from a vial in the drug delivery apparatus; and delivering the drug in accordance with the treatment information from the data carrier (col. 4, lines 18-33).



Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-4, 7, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al.

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14. Wolf et al. teaches a drug package comprising: a drug vial 140 containing drugs; an electronic data carrier 110 separate from the drug vial; wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of the drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the drug which is to be delivered; the number of treatments available from the drug package; wherein the data carrier is arranged to supply drug treatment information to a drug delivery device a number of times corresponding to the number of treatments available (fig. 10, 1035); and wherein the data carrier includes a memory. It should be noted that Wolf et al. fails to teach a plurality of vials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a plurality of vials, since it has been held that mere duplication of the parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

15. Claim 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romick

16. Romick teaches the drug package according to claim 1. It should be noted that Romick fails to teach wherein the data carrier is a radio frequency device. However, it is old and known in the art to use a radio frequency device as a means for transferring data as evidenced by Castellano et al. (col. 9, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a radio frequency device as an alternative means for transferring data.

17. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. in view of Wolf et al.

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18. Castellano et al. teaches the drug delivery apparatus according to claim 13. It should be noted that Castellano et al. fails to teach wherein the drug delivery apparatus includes an authorization portion which prevent delivery if any of the treatment information indicates that the drug is unsuitable for delivery. However, Wolf et al. teaches wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Castellano et al. to include the authorization portion of Wolf et al. to insure proper activation (col. 11, lines 24-34).

19. Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Eigler et al. 6328699.

20. As to claim 22, Wolf et al. teaches a drug deliver device comprising:
a delivery portion for delivering a drug to a patient 140;
a drug use analyzer which records the use of the drug over a number of treatments as recorded treatment information, which analyses to amount of a drug delivered over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains (col. 13, line 52-67). It should noted that Wolf et al. fails to teach a repeat prescription ordering portion which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that

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the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient. However, Eigler et al. does teach a repeat prescription ordering portion (col. 10, lines 60-65) which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient (col. 10, lines 8-45). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the repeat prescription ordering portion of Eigler et al. to ensure that the user has a new supply of the drug before the drug in the device is exhausted and to insure the proper amount of drug is being used.

21. Wolf/Eigler teaches wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription (col. 13-26); wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered (col. 10, lines 60-65); wherein the drug use analyzer includes a counter for counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the drug analyzer includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, lines 52-67); wherein the drug use analyzer includes a comparator which compared the number of drug

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treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a repeat prescription order signal when only a certain proportion of the prescribed drug remains (col. 13, lines 52-67); wherein the repeat prescription re-ordering portion orders a repeat prescription once it received a repeat prescription order signal from the drug use analyzer (col. 10, lines 60-65); wherein the drug use analyzer includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, line 52-67); wherein the memory for holding the total number of drug treatments is located in the data carrier (col. 13, lines 52-55).

22. As to claim 31, Wolf/Eigler teaches a method of prescribing a drug, comprising: supplying a patient with a course of a number of drug treatments 623 for administering using a drug delivery device; recording the use of the drug treatments (col. 13, lines 35-39); analyzing the use of drug treatments; identifying when only a certain proportion of the drug treatments remains (col. 13, line 52-67); and submitting the recorded treatment information to a data center once only the certain proportion of the drug treatments are identified as remaining (col. 10, lines 60-65); analyzing the recorded treatment information of the data center according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specification have not been satisfied, referring the patient to a doctor (col. 10, lines 8-45); issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order (col. 10, lines 60-65); wherein the electronic ordering is done via a modem connection to a telephone line (col. 13, line

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23-26); wherein the electronic ordering is done via a connection to an electronic network (col. 10, lines 60-65); wherein the analyzing of the use of the drug treatments includes counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the analyzing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied (col. 13, lines 52-67); further including the step of generating a repeat prescription order signal when it is identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65); and further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments (col. 13, lines 52-67).

Allowable Subject Matter

23. Claims 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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MM



**GLENN K. DAWSON
PRIMARY EXAMINER**